June 21, 2024

Tactile Medical
℅ Charmaine Dwyer
Managing Director
The Tamarack Group-MPLS, LLC
23730 Lawtonka Drive
Shorewood, Minnesota 55331

Re: K234155
Trade/Device Name: Nimbl (model PD08-N1)
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible limb sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: May 22, 2024
Received: May 22, 2024

Dear Charmaine Dwyer:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Nicole M. Gillette -S

Nicole Gillette
Assistant Director
DHT2B: Division of Circulatory Support,
Structural and Vascular Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K234155

Device Name

Nimbl (PD08-N1)

Indications for Use *(Describe)*

The Nimbl system is intended for use by medical professionals and patients who are under medical supervision, for the treatment of the following conditions:
- Chronic edema
- Lymphedema
- Venous insufficiency
- Wound healing

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Nimbl

Prepared May 1, 2024

Submitter

Manufacturer:

Tactile Medical
3701 Wayzata Blvd, Suite 300
Minneapolis, MN 55416

Contact Person:

Vishal Agarwal, Senior Manager – Quality & Regulatory
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612-800-5535

Device

Device Name:	Nimbl (model PD08-N1)
Common / Usual Name:	Pneumatic compression device
Classification Name:	Compressible limb sleeve (21 CFR 870.5800)
Product Code	Sleeve, limb, compressible (JOW)
Device Regulatory Class:	Class 2

Predicate

Device Name:	Entre (model PD08-U)
Premarket Notification Number:	K143185

Device Description

The Nimbl system is a pneumatic compression device that delivers intermittent sequential compression treatment to affected extremities for lymphedema, chronic edema, venous insufficiency, and wound healing.

This device helps direct and move excess fluid from an impaired lymphatic region to healthy regions, where fluid can be absorbed and processed naturally by the body. The Nimbl controller is used to inflate the connected garment chambers in a pre-programmed sequence from the distal end to the proximal end of the patient. The pressure gradient provides higher distal pressures. This creates a dynamic wave of therapy that directs fluid into the lymphatic capillaries while maintaining distal pressure to prevent distal backflow. The patient's healthcare provider determines what pressure setting is appropriate for the patient.

Indications for Use

The Nimbl system is intended for use by medical professionals and patients who are under medical supervision, for the treatment of the following conditions:

- Chronic edema
- Lymphedema
- Venous insufficiency
- Wound healing

The subject and predicate devices have the same intended use and are both prescription devices.

Comparison of Technological Characteristics with the Predicate Device

The Nimbl device and the predicate Entre device are pneumatic compression devices that utilize the same fundamental technology, mode of action, and principles of operation. They are based on the same basic design, software/firmware, hardware, and materials, and device features are similar. They both require a power source for operation. A high-level comparison is provided below.

	Nimbl (model PD08-N1) system (subject device)	**Entre (model PD08-U) system** (predicate device)	**Comparison**
Product Type	Pneumatic compression device	Pneumatic compression device	Same
Components	Controller Garments Hoses Power adapter External battery	Controller Garments Hoses Power adapter	The subject device has the option of battery power supply; the predicate does not have this feature.
Mode of Action	Helps direct and move excess fluid from impaired lymphatic regions to healthy regions, where fluid can be absorbed and processed naturally by the body.	Helps direct and move excess fluid from impaired lymphatic regions to healthy regions, where fluid can be absorbed and processed naturally by the body.	Same
Principles of Operation	The controller inflates the connected garment chambers in a pre-programmed sequence from distal to proximal with a pressure gradient that provides high distal pressures. The garment chambers are sequentially inflated, pressure is held, and then all chambers are deflated simultaneously.	The controller inflates the connected garment chambers in a pre-programmed sequence from distal to proximal with a pressure gradient that provides high distal pressures. The garment chambers are sequentially inflated, pressure is held, and then all chambers are deflated simultaneously.	Same
Environment of Use	Hospital, clinical, and home settings	Hospital, clinical, and home settings	Same
Device Lifetime	5 years	5 years	Same
Controller Size and Weight	8.0” x 5.5” x 2.0” 1.75 lbs	11.0” x 6.0” x 8.0” 4 lbs	The subject device is smaller and weighs less

	Nimbl (model PD08-N1) system (subject device)	**Entre (model PD08-U) system** (predicate device)	**Comparison**
			than the predicate, primarily due to its smaller compressor.
Electrical Requirements	100 Vac – 264 VAC, ~50/60 Hz 10.9 V rechargeable battery pack	100 Vac – 240 VAC, ~47/63 Hz	The subject and predicate devices have similar power requirements.
Controller Enclosure Material	Plastic	Plastic	Same
User Interface	Push buttons (silicone pad with carbon puck)	Push buttons (membrane switch)	Same
Wireless Functions	Bluetooth	None	The subject device has Bluetooth capability for optional use with the designated mobile application; the predicate device does not have this feature.
Software / Hardware Type	Analog and digital electronics with microprocessor	Analog and digital electronics with microprocessor	Same
Software-Concern Level	Basic Documentation Level	Moderate Level of Concern	Same Minor software updates have been made.
Pressure Range	19-60 mmHg	20-80 mmHg	Similar; upper limit lowered for patient comfort.
Output	Sequential gradient pressure	Sequential gradient pressure	Same
Dwell Time	25 seconds minimum	25 seconds minimum	Same
Treatment Time	1 hour maximum	1 hour maximum	Same
Garment Chamber Pressure Control	Pressure based	Pressure based	Same
Garment-Controller Connections	Optional detachable tether hose and new connectors	No detachable tether hose	The subject device features new connectors on the garment and controller, and an optional tether hose, compared to the predicate.
Garment Port	New port design	Older port design	Similar; the port snout and base design has been updated.
Garment Materials	Nylon fabric Polyurethane coated polyester fabric	Nylon fabric Polyurethane coated polyester fabric	Same
Garment Chambers	8	8	Same

	Nimbl (model PD08-N1) system (subject device)	**Entre (model PD08-U) system** (predicate device)	**Comparison**
Device Cleanability	Cleanable using commonly available mild household products and disinfectants.	Cleanable using commonly available mild household products and disinfectants.	Same

Technological differences, resulting from modifications made to the predicate device, include:

- Bluetooth connectivity for optional use with the Kylee Mobile App to transfer usage data, supporting user ability to log treatments in the mobile application.
- an external battery to support portability.
- a smaller controller to support portability.
- garment-controller connection updates to support portability.

These differences do not raise any different questions of safety or effectiveness for the Nimbl system compared to the predicate device.

Performance Data

Based on the modifications made to the predicate device, the following types of testing have been completed for the Nimbl device to support the substantial equivalence determination:

- Electrical safety and electromagnetic compatibility (EMC) testing, following IEC 60601-1 Medical electrical equipment – General requirements for basic safety and essential performance
- Software verification and validation (including cybersecurity), following IEC 62304 Medical device software – Software life cycle processes
- Mechanical bench testing, including pressure verification, port strength, and component life testing
- Usability testing
- Environment and distribution testing

The technological comparison and performance testing together demonstrate that Nimbl has a similar safety and effectiveness profile as the predicate device.

Conclusion

The Nimbl device is substantially equivalent to the legally marketed predicate device.